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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/659,869	09/11/2003	Joan T. Odell	BB1294USCNT	6089

23906 7590 07/19/2006

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EXAMINER	
IBRAHIM, MEDINA AHMED	
ART UNIT	**PAPER NUMBER**
1638	

DATE MAILED: 07/19/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/659,869	ODELL, JOAN T.	
	Examiner	Art Unit	
	Medina A. Ibrahim	1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *04/24/06*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *17-29* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *17-29* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Applicant's response filed 04/24/06 in reply to the Office action of 10/19/05 has been entered. Claim 17 is amended. The Declaration under 37 CFR 1.132 of Joan T. Odell and IDS of 04/24/06 have been considered.

In view of the papers filed 04/24/06, the inventorship in this nonprovisional application has been changed by the deletion of Rebecca E. Cahoon, Yiwen Fang, and Zude Weng.

All previous objections and rejections not set forth below have been withdrawn in view of Applicant's amendment.

Claims 17-29 are pending and are under examination.

Claim Rejections - 35 USC § 112

Claims 17-29 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the isolated polynucleotide comprising the full complement/antisense of the nucleotide sequence of SEQ ID NO: 35, a vector comprising said polynucleotide, cell/plant transformed with said vector, and a method of transforming plant/cell with said polynucleotide, does not reasonably provide enablement for the complements or the antisense to all nucleotide sequences encoding polypeptides having at least 95% sequence identity to SEQ ID NO: 36 and their uses in a transgenic plant. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the

invention commensurate in scope with these claims. This rejection is repeated in part for the reasons of record as set forth in the last Office action of 10/19/05. Applicant's arguments filed 04/24/06 have been fully considered but are not deemed persuasive.

The Declaration of Joan T. Odell has been considered and is found persuasive with regard to the enablement of nucleotide sequences encoding SEQ ID NO: 36 and the complement or the antisense to SEQ ID NO: 35. The complement of a nucleotide sequence implies antisense inhibition activity by said nucleotide sequence. The Declaration is not persuasive with respect to the complements or the antisense activity of all nucleotide sequences encoding polypeptides having 95% sequence identity to SEQ ID NO: 36 in a transgenic plant. The Declaration provides that the expression of SEQ ID NO: 35 or the full complement thereof in a transgenic plant would alter plant anthocyanin production. However, the neither declaration nor the instant specification provides any evidence that suggests complements of all nucleotide sequences encoding polypeptides having 95% sequence identity would alter anthocyayin production pathways.

The instant specification is not enabling for antisense inhibition of the nucleotide sequences as broadly claimed in claim 17, part (b). The specification teaches the complement/antisense of SEQ ID NO: 35. The specification does not provide guidance for the obtention and use of all antisense sequences to all nucleotide sequences encoding polypeptides having 95% sequence identity to SEQ ID NO: 36. The state of the art teaches that a high level of sequence identity must exist between the antisense sequence and the target molecule for effective inhibition of expression to occur. Given

the degeneracy of the code, many of the nucleic acids that encode SEQ ID NO: 36 or sequences having 95% identity thereof share relatively little sequence identity, and are significantly divergent from the nucleic acid of SEQ ID NO: 35. Applicant provides no guidance for inhibition of nucleic acids other than SEQ ID NO: 35 by antisense technology, and Applicant teaches no other target nucleic acids that are endogenous to Glycine max.

In Genentech Inc v. Novo Nordisk A/S (42 USPQ2d 1001 at p. 1005). The CAFC stated, "(P)atent protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable....While every aspect of generic claim certainly need not have been carried out by an inventor, or exemplified in the specification, reasonable detail must be provided in order to enable members of the public to understand and carry out the invention....[w]hen there is no disclosure of any specific starting material or conditions under which a process can be carried out, undue experimentation is required...." In this case Applicant has provided no guidance regarding antisense inhibition activity of any of the nucleotide sequences of the claim 17. The prior art does not amend the deficiency. Therefore, Applicant is expecting others to determine the effect of the complements of all nucleotide sequences encoding polypeptides having 95% sequence identity to SEQ ID NO: 36 through the myriad of transgenic plants transformed with each of these nucleotide sequences. Under the guidelines set forth in *Genentech*, this constitutes under experimentation. See In re Wands 858 F.2d 731, 8USPQ2nd 1400 (Fed. Cir, 1988). See also *in re Fischer, 166 USPQ 19 24 (CCPA 1970)* where the court has

determined that the scope of the claims must bear a reasonable correlation with the scope of the enablement. In this case, the enablement is limited to the complement or antisense of SEQ ID NO: 35.

Therefore, for all the reasons stated above the claimed invention is not enabled throughout the broad scope.

Remarks

No claim is allowed.

Contact information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Medina A. Ibrahim whose telephone number is (571) 272-0797. The Examiner can normally be reached Monday -Thursday from 8:00AM to 5:30PM and every other Friday from 9:00AM to 5:00 PM. Before and after final responses should be directed to fax nos. (703) 872-9306 and (703) 872-9307, respectively.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Anne Marie Grunberg, can be reached at (571) 272-0975.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

7/6/06
Mai

MEDINA A. IBRAHIM
PRIMARY EXAMINER